REMARKS

The pending final Office Action addresses and rejects claims 1-13 and 15-21. Claims 1-13 and 15-19 are rejected, and claims 20-21 are withdrawn from consideration.

Claim Amendments

Claim 9 is amended to recite an insertion tube having a funnel-shaped proximal end, a distal end and a hollow passageway extending therebetween. Support for this amendment can be found throughout the specification, for example, in paragraph [0011]. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

Claims 1-3, 6, 9-11, and 16 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,447,489 of Peterson. Applicants respectfully disagree.

Claims 1-3 and 6

Independent claim 1 recites a device for arthroscopically delivering a tissue scaffold to a damaged or injured tissue site. The device includes a first component for receiving and dispensing the tissue scaffold having a funnel-shaped proximal end, a distal end, and an elongate, hollow body extending therebetween. The elongate body defines a passageway extending from the flared proximal end to the distal end. A second component has an elongate body with a tip at a distal end, with the elongate body being configured to be removably disposed within the first component for sliding along the passageway.

Peterson is directed to a laparoscopic access catheter (12) with a seal therethrough to maintain pressure within a body cavity. To form the seal through the cathether, the catheter (12) includes a flexible sleeve (20), present inside of and extending the length of the catheter (12). The flexible sleeve (20) is designed to be filled with a gas that fills the cavity (26), causing the sleeve to collapse inward to seal the channel through the catheter (12). This seal is essential to the operation of the device, thus it is maintained during insertion of instruments, or any device, through the catheter (12) as the sleeve (20).

In this way the sleeve creates a seal within the catheter to prevent gas from escaping through the catheter from a body cavity during surgical procedures. Removal or inactivation of the sleeve such that it could not form the seal within the catheter would render the Peterson device inoperable.

Peterson fails to anticipate the claimed invention because it does not teach or suggest a first component for receiving and dispensing the tissue scaffold having a funnel-shaped proximal end, a distal end, and an elongate, *hollow* body extending therebetween, as required by independent claim 1. The Examiner asserts that the catheter (12) corresponds to the claimed hollow body. Clearly, the catheter (12) is not hollow, as required by claim 1. The term "hollow" is defined as "having a space or cavity inside; not solid; empty" (http://dictionary.reference.com/browse/hollow). The catheter (12) cannot be hollow as it includes the sleeve (20) within the catheter, the specific purpose of which is to *close off the interior* of catheter (12). Thus while the claimed elongate body is hollow, in part to allow the tissue scaffold to be moved therethrough for placement within the body, the catheter (12) of Peterson is never hollow, due to the presence of the sleeve (20) inside the catheter. FIG. 12 of Peterson clearly illustrates how this reference fails to satisfy all limitations of claim 1. The sleeve (20) which is not labeled in FIG. 12, occludes the interior of the catheter (12), creating a condition that precludes it from disclosing the claimed "hollow body."

Accordingly, independent claim 1, as well as claims 2-3, 6 which depend therefrom, distinguish over Peterson.

Claims 9-11 and 16

Independent claim 9 recites an instrument for arthroscopically delivering a tissue scaffold to a damaged or injured tissue site. The instrument includes an insertion tube having a funnel-shaped proximal end, a distal end and a hollow passageway extending therebetween. An insertion rod has an elongate shaft extending into a handle at a proximal end and a blunt tip at a distal end. The elongate shaft is configured to be removably disposed within the insertion tube for sliding along the passageway and contacting the tissue scaffold disposed within the insertion device.

Again, Peterson does not teach or suggest an insertion tube having a funnel-shaped proximal end, a distal end and a *hollow* passageway extending therebetween, as required by amended independent claim 9. As explained above, the catheter (12) includes the sleeve (20) disposed therein and attached thereto for forming a seal a through the catheter (12), thus occluding the interior of the catheter in the manner shown in Peterson's FIG. 12. For the reasons discussed above while addressing claim 1. The catheter (12) cannot have a *hollow* passageway because of the presence of the sleeve (20) within the catheter (12). Thus, the passageway through the catheter (12) is not hollow as required by claim 9.

Accordingly, independent claim 9, as well as claims 10-11, and 16 which depend therefrom, distinguish over Peterson.

Claim Rejections under 35 U.S.C. §103

(1) Peterson

Claims 4, 7, 15, 17, and 18 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Peterson. Claims 4 and 7 depend from claim 1, and claims 15 and 17-18 depend from claim 9, and thus distinguish over Peterson for at least the same reasons discussed above. Claims 4, 7, 15, 17, and 18 therefore represent allowable subject matter.

(2) Peterson in view of U.S. Publication No. 2002/0002360 of Orth et al.

Claims 5 and 12-13 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Peterson in view of U.S. Publication No. 2002/0002360 of Orth et al.

Claim 5 depends from claim 1, and claims 12-13 depend from claim 9, and thus distinguish over Peterson at least because Orth fails to remedy the deficiencies of Peterson. The Examiner evidently recognizes this as Orth is relied upon as a secondary reference only for its disclosure of a cannula diameter. Clearly, no person having ordinary skill in the art would modify the device of Peterson to include a hollow catheter (12), such as with the expandable sleeve (10) of Orth. As explained above, the catheter (12) of Peterson is specifically designed to include the sleeve (20) to allow a seal to be formed

through the catheter (12) by inflating the cavity within the catheter (12) to collapse the sleeve (20) inward. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. See MPEP 2144. Not only would there be no beneficial result from making the catheter hollow, but this modification would actually remove an important feature from the device, namely the ability to seal the catheter. Accordingly, there is simply no advantage to modifying the design of Peterson to include a hollow catheter.

Claims 5 and 12-13 therefore distinguish over Peterson and Orth and represent allowable subject matter.

(3) U.S. Patent No. 6,328,715 of Dragan et al. in view of Peterson.

Claims 1-4, 6, 7, 9-11, and 15-18 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,328,715 of Dragan et al. in view of Peterson. The Examiner asserts that Dragan discloses the claimed invention except for teaching "that the proximal end of the first component is funnel-shaped." The Examiner relies on Peterson to teach a "first component (10) with a funnel-shaped proximal end (14)." Applicants disagree.

There is no motivation to modify the teachings of Dragan, and it is improper for the Examiner to attempt to modify the proximal end of barrel (28) of Dragan to have a funnel shape. The device of Dragan is a syringe used to dispense low-viscosity material, and modifying the flange (30) of the barrel (28) into a funnel shape would serve absolutely no purpose, except possibly to render the device needlessly larger and bulkier. The barrel (28) and the plunger (26) of the device of Dragan are specifically formed to allow the plunger (26) to be moved within the barrel (28) to control the dispensing of material from the ampule (10) positioned within the distal end of the barrel (28). The proximal end of the barrel (28) is substantially linear with the rest of the barrel (28) to maintain proper positioning of the plunger (26) when it is moved within the barrel (28). Modifying the proximal end of the barrel (28) to have a funnel shape would decrease the control over the plunger (26) inside the barrel. Specifically, if the end of the barrel was funnel-shaped, the proximal portion of the plunger (26) would have a larger radius of motion at the proximal end of the barrel, leading to a decrease in the control of

the movement of the plunger and a decrease in the effectiveness of the plunger in dispensing material from the ampule. If one were to attempt to eliminate all of these drawbacks to the Examiner's proposed modification of Dragan, a larger, bulkier tool would need to be constructed, which itself is a disadvantage. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. See MPEP 2144. The facts presented here are just the opposite the proposed modification would change the principle of operation of Dragan as well as create a less desirable device. As explained in MPEP §2143.01, "[i]f the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

For all of these reasons, the Examiner's obviousness rejection based on the combination of Dragan and Peterson must be withdrawn. Independent claims 1 and 9, as well as claims 2-4, 6, 7, 10-11, and 15-18 which depend therefrom, therefore distinguish over this combination of references.

(4) Dragan in view of Peterson and in further view of Orth.

Claims 5, 12, and 13 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Dragan in view of Peterson and in further view of Orth.

Claim 5 depends from claim 1, and claims 12-13 depend from claim 9, and thus distinguish over Dragan and Peterson for at least the same reasons discussed above. Orth fails to remedy any of the deficiencies of Dragan and/or Peterson. Accordingly, claims 5 and 12-13 represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

By Jaime L. Burke

Jaime L. Burke
Registration No.: 61,959
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
617-439-2888
617-310-9888 (Fax)
Attorney for Applicant

1826835.1